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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,799	03/24/2004	Randall K. Wetzel	CST-214	4415

7590 09/23/2009

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EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	

MAIL DATE	DELIVERY MODE
09/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,799	WETZEL ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-15* is/are pending in the application.

4a) Of the above claim(s) *9-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant cancels claim 5.

Accordingly, claims 1-4, 6-8, 15 are examined in the instant application.

Withdrawn Rejection

Objection to the drawing and 102 rejection are withdrawn, in view of the amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-7, 15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Denderen et al, 1989, J Exp Med, 169:87-98, IDS of 06/14/05, as evidenced by WO/200269900-A2 (Fritz et al, 09/12/2002), Denderen et al, 1993, Leukemia and Lymphoma, 11: 29-32, IDS of 06/14/05, and US 5,369,008 (Arlinghaus et al, filed on 11/12/1993), and in view of US 6,617,119 (Prusiner et al, filed on 07/09/2001), for reasons already of record in paper of 4/9/08.

The response asserts as follows:

None of the cited references, alone or in combination, teaches the monoclonal antibodies of the present claims. Nor do they, alone or in combination, suggest the claimed antibodies. Denderen I, as evidenced by Fritz, Denderen II, and/or Arlinghaus, describes a polyclonal

antibody that allegedly binds to a human BCR-ABL fusion protein. However, nowhere does Denderen I, as evidenced by Fritz, Denderen II, and/or Arlinghaus, teach or suggest a monoclonal antibody with the attributes of that covered by the current claims. Or does Prusiner cure this deficiency. Prusiner merely describes a polyclonal antibodies and monoclonal antibodies, both of which are specific to a conformation of a protein. Prusiner nowhere teaches or suggests an antibody, monoclonal or even polyclonal, that specifically binds to human P210 BCR-ABL fusion protein (SEQ ID NO: 1), but does not bind wild type BCR or wild-type c-ABL. Thus, 'Applicants respectfully aver that the collective teachings of the cited references, namely Denderen I, Fritz, Denderen II, Arlinghaus, and Prusiner, are of a polyclonal antibody that allegedly binds to a human BCR-ABL fusion protein. Applicants respectfully aver that a polyclonal antibody cannot render a monoclonal antibody having the same specificity obvious to the ordinarily skilled artisan. The amount of time and effort involved in generating a monoclonal antibody is much larger than that required to generate a polyclonal antibody. Nor is there any guarantee that a monoclonal antibody could be generated or, if such a monoclonal antibody could be generated, that its selectivity for its specific site would be higher than that of the polyclonal antibody. Were that the case, since the generation of monoclonal antibodies is very well known in the art (e.g., the inventors of the technique to generate monoclonal antibodies were awarded the Nobel Prize in 1984 for their efforts), all commercially available antibodies would be monoclonal antibodies. However, many commercially available antibodies are polyclonal antibodies. Two examples of such commercially available polyclonal antibodies attached hereto as Appendix B and Appendix C .

The submission of the references in Appendixes B-C is acknowledged.

The response has been considered but is not found to be persuasive for the following reasons:

The synthetic 10 amino acid peptide containing the specific joining region of P210 BCR-ABL for making the polyclonal antibody specific for said joining region is taught by Denderen et al, 1989 (p.89). Said antibody does not bind to wild type BCR or wild type ABL, as evidenced by WO/200269900-A2 (Fritz et al, 09/12/2002), Denderen et al, 1993, and US 5,369,008. Further, Denderen et al, 1989, teach that the antibodies could recognize the joining region itself or the newly created tertiary b2 or a2 determinants introduced by the bcr-abl joining region (p.95, 4th paragraph).

One would have a reasonable expectation that the monoclonal antibody generated from the synthetic peptide containing the specific joining region of P210 BCR-ABL taught by the combined art would be specific for the joining region of P210 BCR-ABL and does not bind to wild type BCR or wild type ABL, because making monoclonal antibody, including monoclonal antibody to tertiary structure is routine in the art, in view of the teaching of US 5,369,008, and because of the presence of the newly created tertiary structure of the P210 BCR-ABL joining sequence, which is expected to be different from that of the wild type BCR or wild type ABL alone, in view of the teaching of Denderen et al, 1989.

New Rejection Due to the Amendment

Claim Rejections - 35 USC § 112, Second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-8 are indefinite, because they depend on cancelled claim 5.

For the purpose of compact prosecution, claims 6 is interpreted as dependent on claim 1.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
September 19, 2009
/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643